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No. 02-1007

In the Supreme Court of the United States

DUKE UNIVERSITY, PETITIONER

v.

JOHN M. J. MADEY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether petitioner is entitled to summary judgment on respondent's claim of patent infringement under 35 U.S.C. 271(a), on the ground that petitioner's unauthorized use of respondent's patented inventions is protected under the common law defense of experimental use.

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INTRODUCTION

This brief is submitted in response to the order of this Court inviting the Solicitor General to express the views of the United States. The position of the United States is that the petition for certiorari should be denied. The court of appeals' decision does not directly conflict with prior precedent discussing the boundaries of the common law experimental use defense to patent infringement. To the extent that petitioner reads the decision to break new ground, the interlocutory posture of this case will afford the lower courts with an opportunity on remand to clarify the scope of the experimental use defense after further factual development concerning the allegedly infringing uses of respondent's patented inventions. The policy concerns raised by petitioner and its amici may be alleviated by such further clarification on remand and, in any event, may be better suited for legislative rather than judicial consideration.

STATEMENT

1. Respondent, an acclaimed physicist, invented the free electron laser (FEL) in the 1980s. During that time, respondent was a tenured professor at Stanford University, where he obtained patents for the two inventions that are at issue in this case. The first patent (the '103 patent) is for a microwave electron gun that is used as an electron source for FELs. The second patent (the '994 patent) is for an FEL oscillator. Pet. App. 2a-3a.

In 1988, respondent accepted an offer for a tenured position in petitioner's physics department. Shortly thereafter, he moved his FEL research laboratory from Stanford to a new laboratory facility on petitioner's campus. The laboratory contains two FELs, known as the "Mark III FEL" and the "Storage Ring FEL," which incorporate the inventions covered by the '103 and '994 patents. Pet. App. 2a, 4a. Respondent served as the director of petitioner's FEL laboratory until 1997, when a dispute led petitioner to remove respondent from that post. Respondent resigned from petitioner's faculty and has continued his academic and research activities at the University of Hawaii. *Id.* at 3a.

After respondent's departure, petitioner has continued to use the Mark III FEL and the Storage Ring FEL. Pet. App. 3a. Petitioner asserts that the equipment is being used for academic purposes, including instruction and research, and not commercial purposes. Pet. 3. The record does not indicate the specific uses that petitioner has made of the FEL equipment, but it is undisputed that petitioner has not obtained a license from respondent to use the inventions covered by the '103 and '994 patents.[1]

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[1] Research that led to respondent's development of the FEL and the patents at issue was funded in part by the federal government. Although not reflected in the record of the instant dispute, the Department of Energy has informed petitioner that the Mark III FEL and related equipment that was part of respondent's FEL laboratory and remains in

2. Respondent brought suit against petitioner for patent infringement and various other federal and state law claims. Respondent claimed, *inter alia*, that petitioner infringed the '103 and '994 patents by using the inventions (as incorporated in the Mark III FEL and the Storage Ring FEL) without his permission. Respondent's infringement claim is predicated on Section 271(a) of the Patent Act, which provides in relevant part that "whoever without authority makes, *uses*, offers to sell, or sells any patented invention * * * during the term of the patent therefor, infringes the patent." 35 U.S.C. 271(a) (emphasis added).

3. The district court entered summary judgment for petitioner on respondent's patent infringement claim. Pet. App. 31a-56a. The court explained that, although unauthorized use of a patented invention is proscribed by the Patent Act, "for well over a century, United States 'patent jurisprudence has paid homage to . . . an exception from infringement liability for . . . unauthorized uses of patented inventions[,]' where the uses were solely for research, academic, or experimental purposes." *Id.* at 40a. The court further stated that the common law experimental use "defense remains viable and may be asserted in those cases in which the allegedly infringing use of the patent is made for experimental, nonprofit purposes only." *Ibid.*

The district court concluded that the experimental use defense is a complete answer to respondent's patent infringement claim. Pet. App. 39a-46a. The court explained that respondent had the burden of proving that petitioner "has *not* used the equipment at issue 'solely for an experimental or other non-profit purpose'" and that petitioner's use of the equipment "had definite, cognizable, and not insubstantial

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petitioner's custody is the property of the United States government. The Department has requested petitioner to transfer the equipment to the University of Hawaii, in order to carry out a federal grant project supporting important domestic security related research.

commercial purposes." *Id.* at 41a (quotations omitted; emphasis added). The court found that respondent failed to meet that burden, explaining that petitioner's "primary purpose is to teach, research, and expand knowledge" and that respondent's "mere speculation that [petitioner] intends, in this case, to stray from [that] general policy * * * is insufficient to create a genuine issue of material fact." *Id.* at 43a.

4. The Federal Circuit reversed in pertinent part and remanded. Pet. App. 1a-30a. The Federal Circuit agreed that the "judicially created experimental use defense" remains available, *id.* at 21a, but it concluded that the district court erred in applying that defense and, "consequently, incorrectly found that there was no genuine issue of material fact upon which [respondent] could prevail," *id.* at 30a. As a threshold matter, the court found, the district court had improperly shifted the burden to respondent "to show as a part of his initial claim that [petitioner]'s use was *not* experimental." *Id.* at 23a (emphasis added). But more fundamentally, the Federal Circuit held, the district court had operated under "an overly broad conception of the * * * experimental use defense." *Id.* at 24a.

The court of appeals explained that, under existing case law, the experimental use defense is "very narrow" and is confined to actions performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." Pet. App. 24a. According to the court, the defense does not insulate "conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications." *Id.* at 25a (citing *Pitcairn* v. *United States*, 547 F.2d 1106 (Ct. Cl. 1976), cert. denied, 434 U.S. 1051 (1978)). That general analysis, the court added, applies both to for-profit and nonprofit entities, including "major research universities," which "often sanction and fund research projects with arguably no commercial application whatsoever." *Ibid.*

The Federal Circuit emphasized that application of the experimental use defense requires "a[] detailed analysis of the character, nature and effect of the use." Pet. App. 25a. The district court in this case, the court found, "attached too great a weight to the non-profit, educational status of [petitioner]." *Id.* at 26a. Indeed, the court of appeals noted, petitioner, "like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream." *Id.* at 26a n.7. The Federal Circuit thus remanded for reconsideration of petitioner's experimental use defense, stating that "[t]he correct focus should not be on the non-profit status of [petitioner] but on the legitimate business [petitioner] is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* at 26a.

DISCUSSION

The petition in this case should be denied. To date, the common law experimental use defense has been applied infrequently by the lower courts and only as a narrow exception to the general statutory prohibition on patent infringement. The Federal Circuit's treatment of that defense in this case is generally in line with the lower court case law that has developed in this area. While petitioner asserts that a more robust exception for experimental use is needed to accommodate university research in particular, the existing case law does not establish such an exception and any substantial altering of the balance between the goals of the patent laws and the demands of academic research calls for judgments that are legislative, not judicial, in nature.

Petitioner argues that the Federal Circuit's decision will render the experimental use defense unavailable to research institutions simply because their "legitimate business" *is* research. Pet. App. 25a. Although some language in the

opinion, in isolation, could support such an argument, that approach is not compelled by the decision when read as a whole. Under the Federal Circuit's decision, research institutions are neither automatically entitled to nor automatically ineligible for the experimental use defense. Thus, to determine whether the experimental use exception applies, the Federal Circuit instructed the district court on remand to consider not simply the legitimate business of petitioner, but the specific uses to which the patented inventions at issue were put. *Id.* at 26a. The record currently does not detail such uses, and that provides another reason to deny certiorari at this interlocutory stage of the case.

A. The Court Of Appeals' Decision Is Not Directly Contrary To Prior Case Law Applying The Experimental Use Defense

1. The Patent Act states that "whoever without authority * * * uses * * * any patented invention * * * during the term of the patent therefor, infringes the patent." 35 U.S.C. 271(a). The text of the Act does not expressly establish an experimental use exception. For some time, however, courts have recognized a limited experimental use exception to the statutory prohibition on the unauthorized use of a patented invention. The court of appeals' application of that judge-made defense in this case is generally in step with prior lower court precedent.

a. The common law experimental use defense traces its origins to an opinion by Justice Story in *Whittemore* v. *Cutter*, 29 F. Cas. 1120 (C.C. D. Mass. 1813). *Whittemore* was a patent case in which the defendant challenged the validity of a jury instruction. In the course of discussing that instruction, Justice Story observed that "it could never have been the intention of the legislature to punish a man, who constructed * * * a [patented] machine merely for philosophical experiments, or for the purpose of ascertaining

the sufficiency of the machine to produce its described effects." *Id.* at 1121. That statement was dictum; the infringing activities at issue in *Whittemore* were not claimed to be experimental in nature and the defendant did not seek to avoid liability on that ground. But Justice Story's observation nonetheless provided the impetus for judicial recognition of an experimental use defense.

Since *Whittemore*, the experimental use defense has had a modest existence. The number of cases in which defendants have invoked the defense is relatively small; the number of times that courts have actually relied on it to excuse otherwise infringing conduct is smaller still; and this Court itself has not addressed the application of the defense. See Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1, 17-18 (2001) ("In practice, * * * the experimental use doctrine has rarely been applied in favor of an accused infringer.").[2]

b. The relatively minor role played by the experimental use defense is consistent with the limits placed on that defense by the text of the Patent Act and policies underlying that Act. The 1952 Patent Act by its terms prohibits any unauthorized "use" of a patented invention, 35 U.S.C. 154

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[2] Although this Court has not addressed the availability or scope of the experimental use defense to a claim of patent infringement, the Court has recognized a "distinction between inventions put to experimental use and products sold commercially," *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998), in the context of determining whether an invention was "in public use or on sale" more than one year before a patent application and thus ineligible for patent protection under 35 U.S.C. 102(b). See, *e.g.*, *Smith & Griggs Mfg. Co.* v. *Sprague*, 123 U.S. 249, 256 (1887). Although the Court's patentability cases do not discuss the exception at issue here, they nonetheless underscore that the determination whether an inventor has engaged in an experimental use may be highly fact specific. See *Root* v. *Third Ave. R.R.*, 146 U.S. 210, 221-226 (1892) (discussing experimental-use determinations in this context).

and 271(a), and does not contain any explicit exception for experimental uses. Cf. 35 U.S.C. 271(e) (exception for uses of certain patented inventions manufactured with DNA), discussed at pp. 16-17, *infra*. This Court has stated that "§ 271(a) of the [1952] Patent Code which defines 'infringement,' left intact the entire body of case law on direct infringement," *Aro Mfg. Co.* v. *Convertible Top Replacement Co.*, 365 U.S. 336, 342 (1961), which would presumably include the judge-made experimental use defense. But even assuming that Congress intended to incorporate existing case law on that defense, Section 271(a)'s express prohibition of any unauthorized "use" of a patented invention precludes any role for an experimental use defense that goes beyond the traditionally narrow confines of the defense.

Similarly, the underlying premise of federal patent law, which is embodied in the Constitution itself, is that "the Progress of Science" is best promoted by giving inventors "the exclusive Right to their * * * Discoveries" during the limited term of a patent. U.S. Const. Art. I, § 8, Cl. 8. By vesting the patent holder with the right to exclude others from making, using, or selling the subject matter of his patent for a limited time, the patent laws provide a powerful incentive for scientific innovation and development. When the public is permitted to engage in the unlicenced use of patented inventions without incurring liability for infringement, even with respect to "experimental" uses that may offer other scientific benefits, the incentives provided by the patent laws are diminished and the nature of the patent "bargain" altered. *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989). The more broadly that the experimental use defense is construed, the greater is the potential adverse impact on the patent bargain.

c. Courts have repeatedly emphasized that the experimental use defense is "narrow." See, *e.g.*, *Embrex, Inc.* v. *Service Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000)

(per curiam) (experimental use defense has been construed "very narrowly"); *Roche Prods., Inc.* v. *Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir.) ("truly narrow"), cert. denied, 469 U.S. 856 (1984); see also Mueller, *supra*, 76 Wash. L. Rev. at 17-18 (same). Typically, the defense is available only when an experiment is undertaken "for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement." *Poppenhusen* v. *Falke*, 19 F. Cas. 1048, 1049 (C.C. S.D.N.Y. 1861). The defense ensures that individuals who experiment *on* a patented device simply to understand how it works will not face liability for patent infringement. Cf. *Whittemore*, 29 F. Cas. at 1121 (defense allows one to "ascertain[] the sufficiency of the machine to produce its described effects"). And thus in effect, the defense has excused only "de minimis" acts of technical infringement. *Embrex*, 216 F.3d at 1349; see *Roche*, 733 F.2d at 863 ("It is obvious here that it is a misnomer to call the [alleged experimental] use *de minimis*. It is no trifle in its economic effect on the parties even if the quantity used is small. It is no dilettante affair such as Justice Story envisioned.").

2. a. Petitioner argues that the Federal Circuit's application of the experimental use defense in this case represents a significant break with prior case law applying the defense. Pet. 13-15. But the standards employed by the Federal Circuit below are drawn directly from prior decisions of the Federal Circuit and its predecessors. As noted, the court's observation that the experimental use defense is "very narrow and strictly limited" (Pet. App. 24a) has been repeatedly recognized by the case law. The principle that the defense is "limited to actions performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" (Pet. App. 24a (internal quotation marks omitted)) was first announced as early as the 1860s and has been reiterated on several occasions since then. See *Poppenhusen*, 19 F. Cas. at 1049; *Roche*, 733 F.2d at 863; *Embrex*, 216 F.3d at 1349. And

the Federal Circuit's refusal to extend the defense to experimental uses that further a defendant's "legitimate business," even when that business is not commercial in nature (Pet. App. 26a), is drawn from *Pitcairn* v. *United States*, 547 F.2d 1106, 1125-1126 (Ct. Cl. 1976). See also *Douglas* v. *United States*, 181 U.S.P.Q. (BNA) 170, 177, aff'd on other grounds, 510 F.2d 364 (Ct. Cl. 1974), cert. denied, 423 U.S. 825 (1975).

b. Petitioner argues (Pet. 13) that the Federal Circuit's recitation of *Pitcairn*'s "legitimate business" language will strip academic institutions of the experimental use defense altogether, explaining that "[n]o research institution will be able to demonstrate that its experimental use of any patent fails to further the institution's 'legitimate business,'" "[b]ecause such entities are 'in the business' of research and education." Pet. 14. Although some language in the court of appeals' decision (see Pet. App. 25a) could support such an interpretation, that interpretation of the decision would produce the anomalous and untenable result of subjecting research institutions to a *disfavored* status under the experimental use defense. Moreover, read as whole, the court's decision is fairly susceptible of a much more routine and evenhanded application of the defense.

Indeed, in remanding the case, the Federal Circuit instructed the district court to focus on not only "the legitimate business [petitioner] is involved in," but also "whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." Pet. App. 26a; see *ibid.* ("The correct focus should be * * * on the legitimate business [petitioner] is involved in *and* whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.") (emphasis added). If engaging in the "legitimate business" of research itself were enough to divest an institution of any experimental use defense, then there would have been no reason

for the court of appeals to have instructed the district court to undertake the second half of the inquiry set forth above.

The fact that the Federal Circuit remanded the case for further consideration of the availability of the experimental use defense and, in particular, the instructions that it gave concerning the "correct focus" (Pet. App. 26a) of the remand indicates that the decision is premised on a much more accommodating view of the application of the experimental use exception in the context of research institutions than the one feared by petitioner. The decision appears to premise the applicability of the experimental use exception on the specific actions of a research university, and not any wholesale determination that such institutions are categorically entitled to or ineligible for the defense. Moreover, at this interlocutory stage of the case, there is no reason to *assume* that the decision below will establish the sort of categorical and discriminatory rule against the application of the experimental use exception in the research-institution setting criticized by petitioner and its amici.

c. Petitioner asserts that, prior to the decision below, "case law [had] established that a research institution did not infringe a patent if it used a patented invention for experimental purposes only." Pet. 12. But the only case cited by petitioner for this "established" rule is a district court decision from 1935 that was reversed on appeal. See *Ruth* v. *Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 703 (D. Colo. 1935), rev'd on other grounds, 87 F.2d 35 (10th Cir. 1936). The United States is not aware of any other reported decision applying the experimental use defense to excuse otherwise infringing activities by a research institution. The present decision is the only one that has ever given extended consideration to how the defense should be applied in that context and the Federal Circuit's remand order leaves that issue open in this case. Accordingly, there is no direct conflict that warrants review by this Court concerning whether,

or when, research institutions in particular are entitled to the benefit of the experimental use exception.

d. At a more general level, petitioner asserts that the Federal Circuit's decision disregards the settled "dichotomy between commercial and non-commercial uses of a patent." Pet. 11. But that dichotomy is hardly clear-cut. During the past 20 years, there has been a growing trend toward the commercialization of academic research.[3] That trend has been accelerated by the enactment of federal laws, such as the Bayh-Dole Act, 35 U.S.C. 200 *et seq.*, that give universities broad latitude to take title to discoveries resulting from federally funded research and to grant exclusive licenses to private companies to commercialize those discoveries. It also reflects the growth of new industries with technological roots, such as biotechnology, software, and microelectronics; the increasing cost of conducting academic research; and federal policies that encourage collaborative university-corporate research activities. See Bok, *supra*, at 11-12; National Academy of Engineering, *supra*, at 98-99; Mueller, *supra*, 76 Wash. L. Rev. at 33-35; Michel, *supra*, 7 High Tech L.J. at 377-378. Thus, universities today are devoting increasing efforts toward the commercial exploitation of scientific research and the record suggests that petitioner itself has joined in that trend. See Pet. App. 26a n.7. There is nothing in the current patent laws to suggest that modern universities—many of which have themselves taken *advantage* of

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[3] See, *e.g.*, Derek Bok, *Universities in the Marketplace: The Commercialization of Higher Education* 57-78 (2003); Louis G. Tornatzky, et al., *Innovation U.: New University Roles in a Knowledge Economy* (2002) (case studies); Jennifer Croissant & Sal Restivo eds., *Degrees of Compromise: Industrial Interests and Academic Values* 55-100 (2001); National Academy of Engineering, *Technology Transfer Systems in the United States and Germany: Lessons and Perspectives* 91-123 (H. Norman Abramson, et al., eds. 1997); Suzanne T. Michel, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 71 High Tech. L.J. 367, 377-378 (1992).

patent protection and entered into licensing arrangements —are somehow outside the class of potential infringers because of an asserted non-commercial status.[4]

In any event, as noted above, in applying the experimental use defense, the Federal Circuit's decision in this case specifically calls for "a[] detailed analysis of the character, nature and effect of the [challenged] use." Pet. App. 25a. That kind of "detailed analysis," and not generalized assertions about the non-commercial or commercial character of academic research or major research universities, should guide the lower courts in this case in determining whether —in the light of a more fully developed factual record— petitioner's uses of respondent's patented inventions are a protected experimental use.

B. Petitioner's Broad Policy Concerns Are Speculative At This Time And Ultimately Are Better Suited For Legislative Rather Than Judicial Consideration

Petitioner argues that if research institutions are compelled by the Federal Circuit's decision to obtain licenses in order to use patented inventions for academic research, critical forms of scientific inquiry will be stunted. Pet. 16-25. But there is no reason to presume that the impact of the Federal Circuit's decision will be as severe as petitioner hypothesizes and, if problems materialize, Congress may be the proper forum to evaluate the problems and devise a comprehensive solution.

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[4] From 1979 to 1997, the number of patents awarded annually to universities increased nearly ten-fold, from 264 to 2,436. Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law & Contemp. Probs. 289, 292 (2003). Today, universities earn more than one billion dollars per year in patent royalties and licensing fees. Bok, *supra*, at 12. Petitioner, "like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream." Pet. App. 26a n.7.

1. Even assuming the Federal Circuit's decision substantially limits the availability of the experimental use defense, there are several reasons why the practical impact of that decision may not be as great as petitioner fears and why review is not warranted at this time to preempt any such potential impact. First, when academic scientists use patented inventions that are available for purchase, such as commercially available laboratory equipment or biological and chemical agents, they may be protected by the "first sale" doctrine. Under that doctrine, the sale of a patented invention by the patent holder carries with it an implied license for the purchaser to engage in the unrestricted use of the invention. See, *e.g.*, *Aro Mfg. Co.*, 377 U.S. at 484; *United States* v. *Univis Lens Co.*, 316 U.S. 241, 249-250 (1942); *Hewlett-Packard Co.* v. *Repeat-O-Type Stencil Mfg. Corp.*, 123 F.3d 1445, 1451-1452 (Fed. Cir. 1997), cert. denied, 523 U.S. 1022 (1998). As a result, when an academic researcher purchases a patented research tool, he is generally free to use it for experimental (or other) purposes.

Second, even in situations where the first-sale doctrine is not applicable, such as with respect to the use of patented processes or methods that are not subject to sale, it is unclear that the unavailability of the experimental use defense will be as disruptive to research efforts as petitioner asserts. Scientific research by America's pharmaceutical, chemical, and electronics industries has proceeded at a rapid and increasing pace even in the absence of the sort of experimental use defense that petitioner claims should be established for academic research institutions.

Third, petitioner's objections ultimately have less to do with the contours of the experimental use defense than with the underlying operation of the patent laws. The concerns identified by petitioner, such as the risk of exorbitant demands by patent holders, the transaction costs associated with obtaining licenses for "stacked" patents, and the un-

availability of inventions that are the subject of exclusive licenses, are not peculiar to the academic research environment; they are present whenever someone wishes to make use of a patented invention, regardless of the use to which the invention will be put. Those concerns inhere in Congress's underlying decision to grant patent holders an unqualified right "to exclude others from making, using, offering for sale, or selling the invention." 35 U.S.C. 154(a)(1).

Fourth, petitioner's arguments ignore the practical consequences that could follow from giving academic research the kind of broad exemption from patent liability sought by petitioner. Recognition of a broad exemption from the patent laws for university research could have significant adverse effects on the incentive structure for inventions that have scientific and research applications. See, *e.g.*, Rai & Eisenberg, *supra*, 66 Law & Contemp. Probs. at 299; Michel, *supra*, 7 High Tech L.J. at 391-397. The problem may be particularly acute with respect to research tools, as to which researchers are "ordinary consumers." If academic researchers are categorically exempt from having to obtain licenses to use such tools, the financial impact on the patent holder may be severe and patent law incentives to innovate may be significantly diminished. See Rai & Eisenberg, *supra*, 66 Law & Contemp. Probs. at 299; Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017, 1035 (1989).

2. This is not to suggest that the academic and scientific community has not raised weighty concerns about the potential effect of the patent laws on academic research. However, any effort to develop a special rule to accommodate academic research within the framework of existing patent law would entail several different layers of policy judgments. For example, choosing the appropriate line between patent protection and the promotion of university research requires a series of judgments, including judgments concerning the

feasibility and cost of licensing arrangements among different types of research and different kinds of patents, the significance of differences in funding sources and commercial outcomes, the make-up of research institutions that might qualify for such assistance, and the respective incentives and disincentives of alternative liability rules.

Congress certainly has the capacity to balance those concerns and, if it perceives a sufficient problem with existing law, to fashion a comprehensive solution. But that would be a much more difficult and ungainly undertaking for the courts in devising or applying an experimental use defense. Indeed, it seems improbable that a 190-year-old, judge-made defense with little rooting in any statutory text could anticipate the challenges of the modern academic and research environment and adequately accommodate the competing policy concerns raised by the parties in this case.

Furthermore, Congress has demonstrated its sensitivity to the sort of policy concerns asserted by petitioner and its ability to address such concerns when it wants to. In *Roche*, the Federal Circuit held that the experimental use defense did not entitle a generic drug manufacturer to conduct experiments with a patented drug in order to prepare a new drug application under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* In response, Congress specifically amended the Patent Act to provide a narrowly tailored exception for the use of inventions "primarily manufactured using * * * site specific genetic manipulation techniques" when used "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. 271(e)(1).

Congress has subsequently entertained several proposals to enact additional exemptions for experimental uses, including one bill that would have established a general exemption for the use of patented inventions "for research or experi-

mentation purposes." See H.R. 5598, § 402, 101st Cong., 2d Sess. (1990) ("It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research or experimentation"); H.R. 1556, § 2, 101st Cong., 1st Sess. (1989) (exemption for reproduction of transgenic farm animals); H.R. 4970, § 2, 100th Cong., 2d Sess. (1988) (exemption for making or use of genetically altered animals "solely for research or experimentation without any commercial intent or purpose"). To date, however, Congress has not enacted any of those proposed bills.

C. The Interlocutory Posture And Unusual Genesis Of This Case Also Counsel Against Granting Review

1. Even when an important threshold question has been decided by a court of appeals, this Court will "generally await final judgment in the lower courts before exercising [its] certiorari jurisdiction." *Virginia Military Inst.* v. *United States*, 508 U.S. 946 (1993) (Scalia, J., respecting the denial of certiorari). That customary practice is well-suited for the interlocutory petition in this case.

If this Court wishes to address the appropriate contours of the experimental use defense, it would benefit from doing so in the context of a fully developed factual record that clarifies precisely how the invention at issue was used by the alleged infringer. The summary judgment record in this case currently lacks such evidence, but the remand ordered by the Federal Circuit will give the parties an opportunity to present additional evidence on that critical factual issue. Regardless of how that evidence is evaluated by the lower courts of remand, its presence in the record would facilitate any subsequent deliberations by this Court on the proper scope of the experimental use exception.[5]

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[5] As discussed above, the Federal Circuit held that the district court had erroneously placed on *respondent* the burden of proving that peti-

2. Moreover, even if the evidentiary record were complete, this experimental use case arises in a somewhat unusual factual context. Infringement claims against university research programs are more likely to be asserted by commercial patent holders or competing research institutions, and when such claims are made, the experimental use defense is likely to have its greatest salience in connection with process and method patents. See *supra*, p. 14. Here, by contrast, the infringement claim against petitioner is being brought by a former employee; the dispute grows out of an employment dispute between respondent and petitioner; and the allegedly infringing activities involve the use of patented devices rather than patented processes or methods. The atypical factual setting of this case provides an additional reason for the Court to deny plenary review at this time and, instead, wait and see if more conventional patent infringement litigation develops in the research-university context in the wake of this case.

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tioner's use of his patented inventions was *not* solely experimental. See Pet. App. 22a-23a. Petitioner has not challenged that aspect of the court of appeals' decision in this Court. The fact that the district court applied an erroneous burden of proof itself may have affected the course of proceedings in the district court and contributed to the lack of factual development concerning the uses to which petitioner has put respondent's inventions. That in itself provides a significant reason to deny the petition and allow for the further proceedings called for by the Federal Circuit before considering whether this Court's review is warranted in this case.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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